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October 30, 2023

The Honorable Paula Xinis  
6500 Cherrywood Lane  
Suite 255  
Greenbelt, MD 20770

**Re: *United States v. Kazem Kazempour*, No. 22-cr-440**

Dear Judge Xinis:

Dr. Kazempour submits this letter to seek the Court's intervention in a discovery dispute. *See* D. Md. Standing Order 2020-01 Discovery in Criminal Cases ¶4.b. Dr. Kazempour has asked the government to produce internal FDA communications related or referring to CytoDyn's 2020 biologic license application ("BLA") for investigational drug Leronlimab as a treatment for HIV. *See* Ex. A. This request includes, but is not limited to, communications about (a) the timing of the BLA, (b) the defendants' roles and responsibilities as to the BLA, (c) CytoDyn's press releases concerning Leronlimab, (d) FDA's determination that it would refuse to file the BLA, and (e) FDA reviewers' opinions of the BLA, CytoDyn, and Amarex. The government has produced a small number of internal FDA emails about CytoDyn and the BLA but has refused to obtain and produce the broader set of requested communications.

The requested discovery should be produced pursuant to Rule 16 and *Brady v. Maryland*, 373 U.S. 83 (1963), because it goes to the core of the government's case against Dr. Kazempour, is likely to support his defense, and is within the government's possession, custody, or control. The government has alleged that Dr. Kazempour submitted the BLA to the FDA knowing that it was incomplete and that the FDA would refuse to file it on that basis. Dr. Kazempour anticipates arguing at trial that neither he nor others at Amarex held this belief and that the FDA refused to file the application for other reasons, including its negative views of CytoDyn and its CEO Nader Pourhassan. As a result, the requested discovery is both material to preparation of Dr. Kazempour's defense and potentially exculpatory. The information is also within the government's possession, custody, or control because the FDA—including individuals who reviewed the BLA—actively cooperated with the government and continue to do so. Under these circumstances, the law requires the government to search for and produce the materials Dr. Kazempour has requested.

**1. The FDA's communications are material to the preparation of Dr. Kazempour's defense and potentially exculpatory.**

Evidence is material under *Brady* if it is favorable to the defense, either as exculpatory or impeachment evidence. *United States v. Parker*, 790 F.3d 550, 558 (4th Cir. 2015). Under Rule 16, evidence is material to preparing a defense if there is "some indication" that the evidence could "significantly ... alter the quantum of proof in [the defendant's] favor." *United States v. Caro*, 597 F.3d 608, 621 (4th Cir. 2010) (internal quotation mark omitted). This bar is met "as long as there

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is a strong indication that [the requested material] will play an important role in uncovering admissible evidence, aiding witness preparation, corroborating testimony, or assisting impeachment or rebuttal.” *Id.* (internal quotation mark omitted). Here, the FDA’s internal communications are material because they likely contain exculpatory and impeachment evidence and other information necessary for the preparation of Dr. Kazempour’s defense.

The FDA’s communications go to the heart of the present charges. The government’s theory is that Dr. Kazempour (the CEO of Amarex) conspired with Dr. Pourhassan (the CEO of CytoDyn) to submit a sham BLA for the use of Leronlimab as an HIV treatment. The indictment alleges that Dr. Kazempour knew that the BLA would be rejected but filed so that Dr. Pourhassan could issue a press release about it, elevating CytoDyn’s stock price. The government reiterated this theory at the recent hearing on defendants’ motion to dismiss. *See, e.g.*, Tr. at 12. At trial, Dr. Kazempour anticipates arguing that (a) he and others at Amarex believed that the FDA would accept the BLA and were surprised when the FDA refused to file the application and (b) that the FDA refused the application in part out of animus towards CytoDyn and Dr. Pourhassan. The BLA, and the FDA’s internal consideration of it, is thus central to this case, as the Court recognized during the recent hearing. *See* Tr. at 61–62 (acknowledging that whether the BLA “was complete or incomplete” was “directly responsive to the allegations”).

The FDA’s internal communications will provide important context for its unexpected rejection of the BLA. The BLA process here lasted over two years and involved multiple FDA employees. These employees undoubtedly exchanged internal communications regarding the timing of the BLA, its content, its sponsors, its likelihood of success, and the ultimate decision to refuse to file. The limited FDA correspondence produced so far supports this as it shows the FDA applied extra scrutiny to CytoDyn’s application.<sup>1</sup> These communications are thus likely to “cut against one of the central allegations in the indictment.” *United States v. Liberto*, No. 19-cr-600, 2021 WL 4459219, at \*7–8 (D. Md. Sept. 29, 2021) (records held by Post Office were material to accused company’s defense because they supported “the possibility of a legitimate reason” for the company telling its subcontractor to hide pricing information from the Postal Service).

## **2. The FDA’s communications are within the government’s possession, custody, and control.**

The government’s duty with respect to criminal discovery is not limited to the evidence in its own hands but extends to that held by “others acting on the government’s behalf.” *Kyles v. Whitley*, 514 U.S. 419, 437 (1995). Evidence is in the government’s possession, custody, or control whenever the government and its agents know of and have access to that evidence. *See United States v. Santiago*, 46 F.3d 885, 893 (9th Cir. 1995). This means that the government must produce “documents in the hands of the prosecutor, any investigative unit under the prosecutor’s control, and any other federal agency allied with the prosecution or involved in the prosecution of criminal litigation.” *United States v. Poindexter*, 727 F. Supp. 1470, 1477 (D.D.C. 1989) (emphasis added).

The government here has had ready access to the FDA’s communications about the BLA. At least once before, the prosecution requested communications from the FDA employees

<sup>1</sup> *See* Ex. B at 2 (FDA employee explaining that she “had been following CYTODYN’s public statements since 2016” and admitting that it was “unusual” to do so); Ex. C at 2 (FDA employee telling CytoDyn’s chief science officer, “[E]xcuse me for being blunt, but I think press releases on this type of data can cause false hope and look sensational. It is also a risk to the company; they might not be prepared for a stampede of requests that they can’t handle.”); *see also* Ex. D at 1 (FDA employee sending “AACCCK!!” to his colleagues in response to email from CytoDyn).

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involved with the BLA, and the employees provided them. *See* Ex. E. This was not a one-off exchange: the FDA is and has been central to this case. The charges against Dr. Kazempour rest on his interactions with the FDA, and the FDA played an active role in the investigation. Its agents gathered records from FDA employees, participated in 38 interviews, including of FDA, Amarex, and CytoDyn employees, and even joined the arrest of Dr. Pourhassan. Indeed, in the government's press release announcing the present charges, an Assistant Commissioner of the FDA's Office of Criminal Investigations thanked "our federal law enforcement partners" for bringing the charges.<sup>2</sup> The prosecution cannot now disclaim this joint relationship to avoid its discovery obligations.

Courts have repeatedly held the prosecution accountable for evidence held by cooperating agencies—including the EPA, *see United States v. W.R. Grace*, 401 F. Supp. 2d 1069, 1082 (D. Mont. 2005); the Postal Service, *see Liberto*, 2021 WL 4459219, at \*7–8; the White House, *see Poindexter*, 727 F. Supp. at 1478; the CIA, *see United States v. Libby*, 429 F. Supp. 2d 1, 10–11 (D.D.C. 2006); the U.S. Trustee, *see United States v. Naegle*, 468 F. Supp. 2d 150, 154 (D.D.C. 2007); and the FDA. In *United States v. Wood*, the defendant was charged with conspiring to defraud the FDA through the unlicensed distribution of a prescription drug. 57 F.3d 733, 735–36 (9th Cir. 1995). The government's expert testified that the substance at issue counted as a prescription drug because it caused hallucinations. *Id.* at 737. Internal FDA materials refuted this testimony. *Id.* at 737–38. The Ninth Circuit held that the prosecutor had a duty to identify and turn over these FDA materials. *Id.* at 737. The court reasoned that because the defendant had been charged under the FDA's statute, the agency was "interested in the prosecution." *Id.* And the FDA had "consulted with the prosecutor in the steps leading to prosecution." *Id.* So, the Ninth Circuit reasoned, "[f]or *Brady* purposes, the FDA and the prosecutor were one." *Id.*

This rule—that the prosecution must produce evidence held by cooperating agencies—further "the purpose and spirit of the rules governing discovery in criminal cases." *Libby*, 429 F. Supp. 2d at 11. "A prosecutor may not sandbag a defendant by the simple expedient of leaving relevant evidence to repose in the hands of another agency while utilizing his access to it in preparing his case for trial." *United States v. Marshall*, 132 F.3d 63, 69 (D.C. Cir. 1998) (internal quotation marks omitted). So it is here. Having "had access in the course of its investigation to extensive" evidence from the FDA and having "benefitted from [its] cooperation," the prosecution "cannot now, in fairness, be permitted to disclaim all responsibility for obtaining [FDA] documents that are material to the preparation of the defense." *Poindexter*, 727 F. Supp. at 1478.

For these reasons, Dr. Kazempour respectfully moves this Court to compel the production of the communications. The parties have agreed that the government may have 14 days to respond to this letter. Counsel is available to answer any questions at the Court's convenience.



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<sup>2</sup> DOJ, *Two Biotech Company Presidents Indicted in Maryland for Securities Fraud Schemes*, (Dec. 20, 2022), <https://www.justice.gov/usao-md/pr/two-biotech-company-presidents-indicted-maryland-securities-fraud-schemes>.